

Tennessee Board of Pharmacy
Board Meeting
July 26-27, 2016

TENNESSEE BOARD OF PHARMACY
665 Mainstream Drive, Iris Room
Nashville, TN
July 26-27, 2016

BOARD MEMBERS PRESENT

Will Bunch, D.Ph., President
Kevin Eidson, D.Ph., Vice President
Michael Dickenson, D.Ph.
Rissa Pryse, D.Ph.
Nina Smothers, D.Ph.
Joyce McDaniel, Consumer Member
Debra Wilson, D.Ph.

STAFF PRESENT

Reginald Dilliard, Executive Director
Stefan Cange, Assistant General Counsel
Terry Grinder, Pharmacy Investigator
Tommy Chrisp, Pharmacy Investigator
Rebecca Moak, Pharmacy Investigator
Scott Denaburg, Pharmacist Investigator
Larry Hill, Pharmacy Investigator
Andrea Miller, Pharmacy Investigator
Sheila Bush, Administrative Manager

STAFF ABSENT

Richard Hadden, Pharmacy Investigator

The Tennessee Board of Pharmacy convened on Tuesday, July 26, 2016, in the Iris Room, 665 Mainstream Drive, Nashville, TN. A quorum of the members being present, the meeting was called to order at 9:05 a.m.

Dr. Dilliard asked for a moment of silence for the Dr. Kendall Lynch, former executive director.

Minutes

The minutes from the May 10-11, 2016 were presented. After discussion, Dr. Eidson made the motion to approve the minutes as amended. Dr. Dickenson seconded the motion. The motion carried.

Office of General Counsel

Mr. Cange informed the board that there are 44 cases for discipline at the Office of General Counsel and 9 of those cases are in litigation.

Mr. Cange stated that the rules from the December 18, 2015 rulemaking hearing were returned by the Attorney General's office. Mr. Cange will make the requisite corrections as soon as possible and prepare the rules for filing.

Mr. Cange informed the board that the RFI/RFGP process is still ongoing. He has been in touch with the Procurement Office and the RFGP will be released as soon as possible.

Mr. Cange asked the board for travel authorization to attend the FARB Regulatory Law Seminar scheduled for September 29-October 2, 2016 in Chicago, IL. Ms. McDaniel made the motion to

authorize travel for Mr. Cange to attend the FARB Regulatory Law Seminar scheduled for September 29-October 2, 2016 in Chicago, IL. Dr. Wilson seconded the motion. The motion carried.

Order of Compliance

Mr. Cange presented the request from Food City #611 to be issued an order of compliance. Food City #611 license was placed on probation for 90 days at the January 10-11, 2016 board meeting. After discussion, Dr. Eidson made the motion to issue an order of compliance to Food City #611. Dr. Smothers seconded the motion. The motion carried.

Complaint Summary

Case 1.

Respondent's employer discovered respondent had been forging prescriptions in her own name and at least one other patient's name. Documentation was obtained to substantiate the allegations. Respondent originally denied allegations but then submitted written request to surrender her pharmacist license due to health issues related to addiction and comorbid condition of mental health issues. TPRN submitted a letter withdrawing advocacy for respondent.

Prior Discipline: Suspended indefinitely, chemical dependence, September, 2011; Reinstated, March, 2012

Recommendation: Accept voluntary surrender

Dr. Smothers made the motion to accept counsel's recommendation. Ms. McDaniel seconded the motion. The motion carried.

Case 2.

Complaint alleged respondent pharmacy has old medication, unlabeled medicines, and some containers with pills of different colors.

BOP Investigator had inspected the respondent pharmacy 2 months prior to the complaint and visited the pharmacy again after receiving the complaint. There were no findings during either visit that would substantiate the allegations. PIC provided a sworn statement denying the allegations.

Prior Discipline: \$1,000 civil penalty paid, counseling violation, March 2014

Recommendation: Dismiss

Dr. Dickenson made the motion to dismiss the complaint. Ms. McDaniel seconded the motion. The motion carried.

Case 3.

Loss Prevention notified BOP of theft of controlled substances by respondent technician resulting in job termination.

BOP Investigator obtained a copy of respondent's voluntary statement admitting to altering prescription quantities and passing the drugs to a female and a male but did not provide names.

Prior Discipline: None

Recommendation: Revoke tech registration

Dr. Wilson made the motion to authorize a formal hearing for revocation. Dr. Pryse seconded the motion. The motion carried.

Case 4.

Complaint filed by PIC that respondent technician failed a pre-employment drug screen by testing positive for THC. PIC reports that respondent never returned and has not returned any phone calls since the test.

Prior Discipline: None

Recommendation: Revoke tech registration

Dr. Smothers made the motion to authorize a formal hearing for revocation. Dr. Eidson seconded the motion. The motion carried.

Case 5.

Loss Prevention notified BOP of theft of controlled substances by respondent technician resulting in job termination and filing of a police report. According to LP report, respondent verbally admitted to stealing and selling 4,000 Hydrocodone and 200 Alprazolam.

BOP Investigator obtained a copy of respondent's voluntary statement admitting stealing and selling "Norco" to earn extra money.

Prior Discipline: None

Recommendation: Revoke tech registration

Dr. Dickenson made the motion to authorize a formal hearing for revocation. Dr. Wilson seconded the motion. The motion carried.

Case 6.

Complaint filed by PIC reporting an empty bottle of Tussionex was found in the pharmacy sink and upon questioning; respondent technician admitted theft for consumption. Police were called and respondent was arrested.

BOP Investigator obtained a copy of respondent's voluntary statement admitting to drinking the cough syrup due to a substance abuse problem.

Prior Discipline: None

Recommendation: Revoke tech registration

Dr. Wilson made the motion to authorize a formal hearing for revocation. Dr. Smothers seconded the motion. The motion carried.

Case 7.

Loss Prevention notified BOP of theft of controlled substances by respondent technician resulting in job termination.

BOP Investigator obtained a copy of respondent's voluntary statement admitting to stealing 350 to 400 Suboxone due to an addiction.

Prior Discipline: None

Recommendation: Revoke tech registration

Dr. Dickenson made the motion to authorize a formal hearing for revocation. Dr. Wilson seconded the motion. The motion carried.

Case 8.

Complainant (spouse of patient) alleged something is wrong with patient's medication or patient is not being told about a medication issue; that a pharmacist ridiculed complainant on several occasions; and the pharmacist ridiculed the complainant once when the complainant reported being shorted 10 tablets.

BOP Investigator visited the respondent pharmacy and obtained sworn statements from PIC and staff pharmacist. Investigator found no other evidence to substantiate any of the allegations.

Prior Discipline: None

Recommendation: Dismiss

Dr. Eidson made the motion to dismiss the complaint. Dr. Smothers seconded the motion. The motion carried.

Case 9.

This is the PIC for Case 8 above.

Prior Discipline: None

Recommendation: Dismiss

Dr. Dickenson made the motion to dismiss the complaint. Ms. McDaniel seconded the motion. The motion carried.

Case 10.

BOP Investigator received relocation application on 4/12/16, performed a relocation inspection 4/18/16 and discovered respondent Oxygen distributor had relocated 2/15/16.

Prior Discipline: None

Recommendation: Civil penalty \$100 for 2 months unlicensed practice site

Dr. Smothers made the motion to authorize a formal hearing with a \$100.00 per month (\$200.00 total) civil penalty for 2 months of practicing at an unlicensed site. Dr. Wilson seconded the motion. The motion carried.

Case 11.

BOP Investigator received relocation application on 4/12/16, performed a relocation inspection 4/18/16 and discovered respondent Oxygen distributor had relocated 12/21/2015

Prior Discipline: None

Recommendation: Civil penalty \$400 for 4 months unlicensed practice site.

Dr. Wilson made the motion to authorize a formal hearing with a \$100.00 per month (\$400.00 total) civil penalty for 4 months of practicing at an unlicensed site. Dr. Smothers seconded the motion. The motion carried.

Case 12.

PIC notified BOP that respondent technician failed a random drug screen by testing positive for oxycodone and opiates without being able to produce a valid prescription. Respondent was fired from the job.

BOP Investigator was unsuccessful in trying to contact respondent. A letter for response was sent by regular mail to the address on file at BOP. It was returned as "Moved Left No Address Unable to Forward."

Prior Discipline: None

Recommendation: Revoke technician registration

Dr. Smothers made the motion to authorize a formal hearing for revocation. Dr. Wilson seconded the motion. The motion carried.

Case 13.

Pharmacy management notified BOP of internal investigation resulting in respondent technician's termination and arrest. A detailed log of video sightings of respondent removing drugs was provided as well as a copy of the police report and warrants. Respondent refused to be interviewed by loss prevention or the police.

Prior Discipline: None

Recommendation: Revoke technician registration

Dr. Eidson made the motion to authorize a formal hearing for revocation. Ms. McDaniel seconded the motion. The motion carried.

Case 14.

Complainant alleged unprofessional conduct by respondent pharmacy continuing to refill and deliver medication to an assisted living facility after being notified to stop.

BOP Investigator reviewed pharmacy records showing a request to hold the medication was entered on 9/21/15 and a courtesy credit was issued. It was refilled 11/23/15 and the patient expired 12/8/15. There is a billing dispute ongoing between respondent and the family of the patient involving balances owed for all the patient's medications. Investigator found no violations of pharmacy laws or rules as it appears to be a financial dispute.

Prior Discipline: None

Recommendation: Dismiss

Ms. McDaniel made the motion to dismiss the complaint. Dr. Pryse seconded the motion. The motion carried.

Case 15.

Spouse of dementia patient complained respondent pharmacy/pharmacists failed to perform proper DUR, failed to properly counsel and filled a prescription multiple times for a medication with a black box warning which resulted in the patient having a drastic decrease in cognition. Complainant alleged that afterward a staff pharmacist was contacted but was not aware of the Black Box Warning and was not able to answer questions about the drug. Caregiver spoke to the PIC the next day and the PIC apologized for not recognizing the problem earlier.

BOP Investigator conducted a thorough investigation involving multiple pharmacies, clinics and pharmacists. Investigator discovered this respondent pharmacy's software requires an override for interactions involving risperidone but it does not list it as a black box warning. Investigator noted that this respondent pharmacy has multiple pharmacists and that many of them had been involved in filling or refilling risperidone for this patient without proper counseling or DUR with the patient or caregiver. Warnings were simply overridden. Based upon the patient's medical history and other prescribed medications, Investigator believes a reasonably prudent pharmacist should have put more thought process into the decision whether to override a warning involving risperidone even if the software did not indicate a Black Box Warning. Investigator believes that enough time should have been taken to adequately counsel the patient or caregiver. Risperidone was filled 7 times, of which 4 times were new prescriptions. Complainant told Investigator that no counseling occurred and she was simply asked if she had any questions about the medication.

During the investigation, Investigator also discovered the patient was being dispensed warfarin and carbamazepine and there were no notes about why the warning was overridden and why the caregiver was not counseled about these medications and possible interactions. There were also no notes indicating the prescriber had been consulted.

Prior Discipline: None

Recommendation: \$1,000 civil penalty for counseling violation

Dr. Smothers made the motion to authorize a formal hearing with a \$4000.00 civil penalty reduced to \$1000.00 with a corrective plan of action for the counseling violation, a Letter of Instruction to the PIC concerning the black box warning and a Letter of Warning for the DUR. Dr. Dickenson seconded the motion. The motion carried.

Case 16.

This is PIC for Case 15 above.

This respondent filled risperidone for the patient as a new prescription 12/12/15 and refilled it 2/7/16. There was no documentation of DUR decisions.

Prior Discipline: None

Recommendation: \$1,000 civil penalty for counseling violation

Dr. Smothers made the motion to authorize a formal hearing with a \$1000.00 civil penalty for failure to counsel and a Letter of Instruction concerning the black box warning. Dr. Eidson seconded the motion. The motion carried. After further discussion, Dr. Dickenson made the motion to authorize a formal hearing with six (6) additional continuing education hours pertaining to therapeutic index drugs. Dr. Wilson seconded the motion. The motion carried.

Case 17.

This is a staff pharmacist for Case 15 above.

This respondent refilled risperidone for the patient 11/5/15. There was no documentation of DUR decisions.

Prior Discipline: None

Recommendation: \$1,000 civil penalty for counseling violation

Dr. Smothers made the motion to authorize a formal hearing with a \$1000.00 civil penalty for failure to counsel and a Letter of Instruction concerning the black box warning. Dr. Eidson seconded the motion. The motion carried. After further discussion, Dr. Dickenson made the motion to authorize a formal hearing with six (6) additional continuing education hours pertaining to therapeutic index drugs. Dr. Wilson seconded the motion. The motion carried.

Case 18.

This is a staff pharmacist for Case 15 above.

This respondent did not fill or refill risperidone for the patient but was the pharmacist that told the caregiver he was not aware of the Black Box Warning and was unable to answer questions appropriately.

Prior Discipline: None

Recommendation: \$1,000 civil penalty for counseling violation

Dr. Smothers made the motion to issue a Letter of Instruction concerning the black box warning. Dr. Eidson seconded the motion. The motion carried. After further discussion, Dr. Dickenson made the

motion to authorize a formal hearing with six (6) additional continuing education hours pertaining to therapeutic index drugs. Dr. Wilson seconded the motion. The motion carried.

Case 19.

This is a staff pharmacist for Case 15 above.

This respondent filled risperidone for the patient 9/9/15 and refilled it 1/2/16. There was no documentation of DUR decisions.

Prior Discipline: None

Recommendation: \$1,000 civil penalty for counseling violation

Dr. Smothers made the motion to authorize a formal hearing with a \$1000.00 civil penalty for failure to counsel and a Letter of Instruction concerning the black box warning. Dr. Eidson seconded the motion. The motion carried. After further discussion, Dr. Dickenson made the motion to authorize a formal hearing with six (6) additional continuing education hours pertaining to therapeutic index drugs. Dr. Wilson seconded the motion. The motion carried.

Case 20.

This is a staff pharmacist for Case 15 above.

This respondent filled the initial prescriptions for risperidone and for carbamazepine. There was no documentation of DUR decisions, no documentation that interactions were considered and nothing to contradict complainant's allegation that counseling did not occur.

Prior Discipline: None

Recommendation: \$1,000 civil penalty for counseling violation

Dr. Smothers made the motion to authorize a formal hearing with a \$1000.00 civil penalty for failure to counsel and a Letter of Instruction concerning the black box warning. Dr. Eidson seconded the motion. The motion carried. After further discussion, Dr. Dickenson made the motion to authorize a formal hearing with six (6) additional continuing education hours pertaining to therapeutic index drugs. Dr. Wilson seconded the motion. The motion carried.

Case 21.

This is a staff pharmacist for Case 15 above.

This respondent filled risperidone for the patient as a new prescription 10/7/15. There was no documentation of DUR decisions.

Prior Discipline: None

Recommendation: \$1,000 civil penalty for counseling violation

Dr. Smothers made the motion to authorize a formal hearing with a \$1000.00 civil penalty for failure to counsel and a Letter of Instruction concerning the black box warning. Dr. Eidson seconded the motion. The motion carried. After further discussion, Dr. Dickenson made the motion to authorize a formal hearing with six (6) additional continuing education hours pertaining to therapeutic index drugs. Dr. Wilson seconded the motion. The motion carried.

Case 22.

BOP was notified by a Sheriff's office that a pharmacy technician had been arrested for drug diversion and the technician was in possession of over 1,000 prescription records, several invoices and some prescription drugs. That technician's registration was revoked. BOP Investigator worked with that SO and DEA to inspect and investigate the pharmacy from which those records and drugs had come. Several violations were cited by DEA and negotiations between respondents and DEA ensued.

DEA issued a Memorandum of Agreement to settle DEA issues with the respondent pharmacy and pharmacist owner.

Findings noted included the following:

13 Controlled substances audited had discrepancies; 4 CSOS records were not maintained as required; 4 purchase invoices did not contain the date of receipt; 7 sales invoices did not contain the name, address and DEA number of both registrants; 727 prescriptions were not being stored at the registered location; 3 thefts of controlled substances were not reported to DEA within one business day.

Settlement conditions in lieu of revoking DEA registration:

\$125,000 settlement amount; respondent will abide by all federal, state and local laws and regulations pertaining to controlled substances; maintain complete and accurate records; conduct CS inventory on a semi-annual basis and conduct accountability audit of 8 controlled substances on a quarterly basis and those 8 drugs and/or strengths will change quarterly; allow DEA personnel entry and inspection at any time without a warrant; notify DEA immediately of any change in status of respondents' state licenses; immediately surrender DEA registration if TN BOP license is suspended, revoked, not renewed, not extended, or not reinstated; immediately notify DEA of any intent to transfer DEA registration to another address.

Prior Discipline: None

Recommendation: 2 years of probation, 2 years of monitoring, provide CS inventories and other information required under DEA settlement to BOP, pay costs of investigation

Dr. Eidson made the motion to authorize a formal hearing for 5 year probation, 5 year monitoring, all opioids inventoried quarterly, submit the information required in the DEA settlement to the board and costs of investigation. Dr. Smothers seconded the motion. The motion carried.

Case 23.

This respondent is the owner/PIC of respondent pharmacy in Case 22 above.

Prior Discipline: None

Recommendation: Reprimand, 2 years of probation

Dr. Smothers made the motion to authorize a formal hearing with 2 years of probation and reprimand. Dr. Wilson seconded the motion. The motion carried.

Case 24.

During a routine sterile compounding inspection, BOP Investigator discovered hormone pellets are being irradiated as Recommendation but media fill testing and endotoxin testing were not being performed as required. Respondent produced some opinions and emails erroneously indicating testing were not required for hormone pellets. Investigator educated the PIC and the pharmacy has since started the required testing. There have been no known issues related to these tests with any of the pharmacy's sterile products, however the potential for harm was there.

Prior Discipline: None

Recommendation: LOW to pharmacy for failure to perform endotoxin testing and media fill testing and to recommend it follow BOP guidance, not personal opinions of management.

Dr. Eidson made the motion to dismiss the complaint. Dr. Dickenson seconded the motion. The motion carried.

Case 25.

Respondent pharmacy technician provided a voluntary statement admitting to stealing controlled substances to self- medicate and try to stop smoking "weed." Tech admitted in writing to stealing 50-60 Alprazolam 2mg, 20-30 Clonazepam 2mg, 10-20 Carisporodol, 20-30 Lorazepam 2mg, 10-20 Diazepam 5mg, 10-20 Diazepam 2mg, 50-60 Zolpidem 12.5mg. Employment was terminated.

Prior Discipline: None

Recommendation: Revoke tech registration

Dr. Wilson made the motion to authorize a formal hearing for revocation. Ms. McDaniel seconded the motion. The motion carried.

Case 26.

Complainant patient alleged respondent pharmacist's refusal to fill pain medications on the date the prescriber indicated when providing multiple prescriptions caused the patient great physical discomfort, exorbitant expense and will continue to disrupt his pain management. Complainant also alleged unprofessional conduct because respondent would not answer questions and refused to show the patient a policy or law stating that the prescription could not be filled and told the patient that he "did not care what date the prescribing physician had placed on the prescription order" so the patient would have to come back "tomorrow."

Respondent pharmacist provided BOP Investigator with a sworn statement that a 28 day supply of IR and ER pain medications were filled 1/21/16 and the prescriber also wrote additional prescriptions for the same medications with an indication to not to fill until 2/17/16. Since the 28 day supply would be due to fill again on 2/18/16, respondent told the patient that he would not fill the prescriptions until the next day.

BOP Investigator also reviewed pharmacy records and CSMD printouts indicating that during the last 12 months, the patient had received 28 days supply of medication on the 28th day 10 times. It had been dispensed 1 day early on 1 occasion and 1 day late on 1 occasion. Investigator did not find any violation of laws or rules.

Prior Discipline: None

Recommendation: Dismiss

Dr. Smothers made the motion to dismiss the complaint. Dr. Dickenson seconded the motion. The motion carried.

Case 27.

Pharmacy PIC notified BOP Investigator on 5/31/16 that respondent pharmacist tested positive for Norfentanyl. Respondent pharmacist had signed a conditional employment agreement 1/4/16 due to previously admitting alcohol/drug abuse to the employer. Respondent pharmacist is currently undergoing treatment and requested to voluntarily surrender the pharmacist's license. The letter of surrender was received at BOP 6/27/16.

Prior Discipline: None

Recommendation: Accept voluntary surrender

Dr. Eidson made the motion to accept counsel's recommendation. Dr. Wilson seconded the motion. The motion carried.

Case 28.

BOP received a copy of DEA 106 form indicating the reporting pharmacy was missing 4,220 Alprazolam 1mg. Loss prevention interviewed respondent technician and provided a signed written statement in which respondent admitted stealing between 10 and 30 Alprazolam 1mg and 90 Amolodipine 10mg for a spouse that did not want to go to the doctor. The internal investigation is ongoing.

Prior Discipline: None

Recommendation: Revoke tech registration

Dr. Dickenson made the motion to authorize a formal hearing for revocation. Dr. Smothers seconded the motion. The motion carried.

Case 29.

During a routine inspection, BOP Investigator educated respondent staff that although radiopharmaceuticals as CSPs are allowed to be compounded in an ISO Class 8 environment as applicable if low-risk, these shall still follow the regulations of a Buffer Area and shall follow the proper requirements of facility design of a seamless smooth floor, ceiling and walls, with no cracks or crevices. Investigator noted the current facility design more appropriately falls under the definition of a Segregated Compounding Area (SCA). As defined, an SCA is a designated space, either a demarcated area or room, that is restricted to preparing low-risk CSPs with 12-hour or less BUD. Such area shall contain a device that provides unidirectional air flow of ISO Class 5 air quality and shall be void of activities and materials that are extraneous to sterile compounding.

Buffer Area:

Tiles are not seamless. Floor is approximately 12 inch square tiles with seams connecting every tile. (Respondent PIC replied his belief that the floor is smooth due to being waxed periodically and is cleaned and disinfected once daily;

Sprinkler heads are not flush with the ceiling;

Ceiling vents are not flush with ceiling;

There is no ISO class ante-area with 40 feet per second displacement method in place for a Buffer Area designation or two room design with an anteroom.;

Room air is not HEPA filtered;

BOP Investigator has reviewed multiple documents and articles indicating White Blood Cell (WBC) tagging is considered medium risk sterile compounding. Respondent replied his belief that WBC tagging

is low risk because it is a radiopharmaceutical and has a 12 hour or less BUD, but stated that HEPA filters will be installed to ensure an ISO Class 7 environment for WBC tagging activities.

Investigator noted that pressure differential gauges are not present and therefore are not logged at least daily.

Soiled ceiling tiles were found in areas outside of the sterile compounding room, which are open to air on one side of the room (not closed in with four walls-approximately 6x6 feet open wall to room where non-sterile functions are performed.) Air moving through the open wall has the ability to move into the sterile compounding area with no gauges of air flow to monitor reverse movement. An air sampling report from August 2015 showed out-of-compliance growth. Fungal and bacterial growth including the "Buffer Room" was noted on the viable air sampling report 2/29/16-3/1/16 (Cladosporium and Yeast). PIC told Investigator that a re-test still produced bio-burden so the open gap will be closed with double doors that will be sealed and retested. An updated response from PIC on 6/29/16 stated that the latest results after implementation of HEPA filters still came back with out-of-compliance growth. On 6/30/16, PIC notified Investigator that pharmacy staff has continued to only compound sterile products labeled with 12 hours or less BUD.

Regarding WBC tagging, PIC indicated that once the pharmacy had installed the HEPA filters, recertified the room to ISO 7, repaired and recertified the two BSC cabinets, the pharmacists again began WBC tagging. PIC indicated that until the second room air testing is completed, pharmacy staff leaves all BSCs and LAFWs on continuously to increase air changes per hour.

Prior Discipline: None

Recommendation: \$1,000 civil penalty for each violation of sterile compounding rules, 1 year of practice monitoring, pay costs of investigation

Dr. Eidson made the motion to issue a cease and desist letter for all operations until the pharmacy is in compliance with USP 797. Dr. Dickenson seconded the motion. The motion carried.

Case 30.

BOP, OIG and Police investigated reports from hospital staff and security alleging that respondent technician verbally admitted to knowingly bringing in at least four forged prescriptions into the outpatient pharmacy to be filled and dispensed. Respondent was terminated and then arrested by police. BOP Investigator tried to contact respondent for a statement, however four possible phone numbers were all out of service and a certified letter to the address given to police was returned and marked "unclaimed." Court dates have been postponed several times. Hospital staff members are willing to testify as to hearing verbal admission by respondent.

Prior Discipline: None

Recommendation: Revoke tech registration

Dr. Dickenson made the motion to authorize a formal hearing for revocation. Dr. Smothers seconded the motion. The motion carried.

Case 31.

PIC notified BOP of technician termination for diversion of controlled substances. Internal investigation included audits and video surveillance showing respondent technician removing Hydrocodone from an automated dispensing machine, placing some in his pocket as well as ingesting some tablets. According to DEA 106 report, 2,275 tablets of Hydrocodone APAP 10/325 and 285 Hydrocodone APAP 5/325 were missing.

BOP Investigator obtained a copy of respondent's voluntary statement. Respondent admitted that over the course of 4 to 5 months, he sporadically took a few Hydrocodone 10 and 7.5 once or twice a week and that this may have sometimes happened more or less. Respondent stated it was for self medicating knee pain.

Prior Discipline: None

Recommendation: Revoke tech registration

Dr. Wilson made the motion to authorize a formal hearing for revocation. Dr. Smothers seconded the motion. The motion carried.

Case 32.

BOP Investigator obtained a copy of a voluntary statement written by respondent tech. Respondent admitted to stealing a bottle of Cipro to treat his girlfriend's urinary tract infection. Respondent was terminated and entered into a restitution agreement.

Prior Discipline: None

Recommendation: Revoke tech registration

Dr. Smothers made the motion to authorize a formal hearing for revocation. Ms. McDaniel seconded the motion. The motion carried.

Case 33.

Respondent MWD is licensed at 3PL site in Tennessee. BOP Investigator inspected the site 10/10/15 and found Respondent in non-compliance with Board Rule 1140-09-.01 (2), (no license displayed.) The site manager and BOP Investigator each sent emails and made phone calls to respondent's corporate office notifying them of the requirement and asking for the license to be sent. After months of not complying, BOP Investigator filed a complaint and notified respondent of the complaint on 5/11/16. The license was received at the 3PL on 5/17/16. From inspection date to compliance date was approximately 7 months.

Prior Discipline: None

Recommendation: \$100 per month for 7 months for non-compliance

Dr. Dickenson made the motion to authorize a formal hearing with a \$100.00 civil penalty (total \$700.00) for 7 months of non-compliance. Dr. Pryse seconded the motion. The motion carried.

Case 34.

Complainant (D.O.) alleged respondent technician forged prescriptions at Respondent's family owned pharmacy, transferred the prescriptions using a different pharmacy's name to another pharmacy, had the prescriptions billed to respondent's insurance, then respondent would pick up the medication and return it to his family pharmacy. This occurred several times before being discovered when the transferring pharmacy called the prescriber for a prior authorization on one of the drugs and prescriber noted that the patient had not been seen since 11/11/14 and had never been placed on most of the drugs. Forged prescriptions included 180 Nexium 40mg, 60 Eliquis 5mg, 45 Nambumetone 500mg, and 30 Lansoprazole.

Prescriber stated that following the discovery, respondent returned to the clinic to ask for refills and admitted the forgeries to the prescriber. Respondent was terminated as a patient.

BOP Investigator obtained a sworn statement from the respondent admitting to the forgeries.

Respondent claimed the Eliquis and Nexium prescriptions were forged due to being out of stock at the family's pharmacy and patients did not want their prescriptions transferred elsewhere.

Prior Discipline: None

Recommendation: Revoke technician registration

Dr. Eidson made the motion to authorize a formal hearing for revocation. Dr. Dickenson seconded the motion. The motion carried.

Case 35.

A companion case complaint was opened to Case 34 (above) when the transferring pharmacy realized they had been drawn into a case of forgeries and insurance fraud.

BOP Investigator interviewed staff and obtained statements. In addition to verifying the prescriber's allegations above that the respondent did use his own name and insurance card to transfer fraudulent prescriptions, complainant pharmacy staff informed Investigator that the family pharmacy owner had come to complainant pharmacy to offer payment and stock replacement if the pharmacy would reverse the insurance claims. Complainant pharmacy staff informed the owner that a Board complaint had already been filed and asked him to leave.

Prior Discipline: None

Recommendation: N/A

Dr. Eidson made the motion to dismiss this compliant. Dr. Dickenson seconded the motion. The motion carried.

Case 36.

A companion case to cases 34 and 35 above was opened after it was alleged respondent PIC entered the complaining pharmacy and tried to bring replacement medication so the fraudulent prescriptions could be deleted and the insurance charges could be reversed. Respondent reportedly told complainant pharmacist that the forging employee now knows that what he did was not the correct way to get medication for others.

Respondent told BOP Investigator that the forging employee was instructed to never do that again and was suspended for five days without pay.

Prior Discipline: None

Recommendation: LOW to DPh

Dr. Eidson made the motion to issue a Letter of Warning to the pharmacist for unprofessional conduct and failure to report a violation. Dr. Dickenson seconded the motion. The motion carried. Dr. Pryse was recused.

Case 37.

BOP Investigator performed a periodic sterile compounding inspection at a nuclear pharmacy which also performs White Blood Cell Tagging. Investigator researched articles by several authors including the current expert UPS committee meeting minutes from the April 2016 meeting which indicates WBC tagging is medium risk and that it should be compounded in a true Buffer Area, not a Segregated Compounding Area.

Respondent pharmacy is currently designed as an SCA. Respondent's reply indicated there are no plans to comply with medium risk requirements. Investigator found the following areas of concern in this pharmacy:

Tacky mat in the blood room was completely dysfunctional and appeared that it had not been changed in an extended period.

Medium risk sterile compounding is performed in an area that does not meet Buffer Area ISO Class 7 or better air standards or primary engineering control/facility and design standards.

Pressure differential gauges are not present and therefore are not logged at least daily.

Sink did not produce hot water for hand washing and proper cleaning.

Pharmacist on duty demonstrated the current process for cleansing and garbing which were not compliant with USP 797. No head cover, face cover, or beard cover is used. Proper cleansing was not followed as part of the process since the lab jacket was donned prior to hand washing.

Sterile gloves are not being used.

(Board Investigator saw no technology, process or documentation that appeared to be as good as or better than current USP 797 requirements.)

Investigator discovered that some CSP's are produced with greater than 12 hour BUD which would require medium risk requirements.

Non-essential items such as radios were found in the room that compounds CSP's.

Ceiling tiles were soiled, bulging, torn, and not properly sealed.

Ceiling vents were dirty and rusted.

Several wood fixtures including cabinets, base of walls, and all other bare wood surfaces are showing cracks and crevices.

Windows and doors have been sealed with what appears to be expanding foam which has become cracked, brown colored and dirty.

Technician registry was not available.

Investigator was also informed that Respondent facility performs WBC tagging for more than one patient simultaneously under the same hood.

Prior Discipline: None

Recommendation: Reprimand, \$1,000 civil penalty for each violation of USP 797, 1 year of monitoring, pay costs of investigation

Dr. Eidson made the motion to issue a cease and desist until the pharmacy is compliant with USP 797. Dr. Dickenson seconded the motion. The motion carried. Dr. Pryse was recused.

Case 38.

BOP Investigator performed a periodic sterile compounding inspection at a nuclear pharmacy which also performs White Blood Cell Tagging. Investigator researched articles by several authors including the current expert UPS committee meeting minutes from the April 2016 meeting which indicates WBC tagging is medium risk and that it should be compounded in a true Buffer Area, not a Segregated Compounding Area.

Respondent pharmacy is currently designed as an SCA. Respondent's reply indicated there are no plans to comply with medium risk requirements. Investigator found the following areas of concern in this pharmacy:

Medium risk sterile compounding was being performed in an area that does not meet Buffer Area ISO Class 7 or better air standards or primary engineering control/facility and design standards.

Pressure differential gauges were not present and therefore were not logged at least daily.

There was no ISO 8 anteroom so there was no sink on the clean side of the anteroom for proper handwashing.

Proper garbing was not being performed.

No head cover, face cover, or beard cover were being used.

Sterile gloves were not being used.

(Board Investigator saw no technology, process or documentation that appeared to be as good as or better than current USP 797 requirements.)

Investigator discovered that some CSP's (i.e. Mebrofenin) are produced with greater than 12 hour BUD.

No smoke studies were available.

Buffer area tiles were not seamless.

Sprinkler heads were not flush with ceiling.

Proper cleaning was not being followed in the Buffer area.

Ceiling tile in the office had at least two soiled tiles near the entrance door of the Buffer area.

Technician affidavits were not available during the inspection.

Prior Discipline: None

Recommendation: Reprimand, \$1,000 civil penalty for each violation of USP 797, 1 year of monitoring, pay costs of investigation

Dr. Eidson made the motion to issue a cease and desist until the pharmacy is compliant with USP 797. Dr. Dickenson seconded the motion. The motion carried. Dr. Pryse was recused.

Case 39.

BOP Investigator performed a periodic sterile compounding inspection at a nuclear pharmacy which also performs White Blood Cell Tagging. Investigator researched articles by several authors including the current expert UPS committee meeting minutes from the April 2016 meeting which indicates WBC tagging is medium risk and that it should be compounded in a true Buffer Area, not a Segregated Compounding Area.

Respondent pharmacy is currently designed as an SCA. Respondent's reply indicated there are no plans to comply with medium risk requirements. Investigator found the following areas of concern in this pharmacy:

Buffer area floor was not flush or smooth. Investigators observed surface flaking on the floor.

ISO 8 Anteroom had no line of demarcation.

No head cover, face cover or beard cover was used.

Handwashing and garbing were not being performed in compliance with USP 797.

Persistent activity hand scrub was not being used correctly.

Gowns were being worn for more than one work shift.

Sterile gloves were not being used.

Unsanitized rubber bands were found in the LAFW.

Paper was found stuck to a wall instead of being in a plastic sleeve.

Rust was found on the BSC in the blood room.

Paint was chipping by the sink in the anteroom.

Sink was dirty/soiled and also very shallow making handwashing difficult.

A lab jacket was observed that does not close at the neck.

Shoes were being kept on the clean side of the anteroom and investigator noted a dirty heel on a shoe that appeared to have a non-cleanable surface.

Distilled water was found opened with no expiration or beyond use date noted.

Tape was found on at least two ceiling tiles.

Cotton gauze was found in the buffer area.

Lead blocks were covered with a material that is tearing off the blocks and may cause particulate in the LAFW.

GFT and MF testing was not being performed using sterile gloves.

A duct work crevice from floor to ceiling in the blood room was not caulked and could contribute to bioburden.

Tacky mat appeared to have been neglected for some time.

(Board Investigator saw no technology, process or documentation that appeared to be as good as or better than current USP 797 requirements.)

Prior Discipline: None

Recommendation: Reprimand, \$1,000 civil penalty for each violation of USP 797, 1 year of monitoring, pay costs of investigation

Dr. Smothers made the motion to issue a cease and desist until the pharmacy is compliant with USP 797. Ms. McDaniel seconded the motion. The motion carried. Dr. Pryse was recused.

Case 40.

BOP Investigator performed a periodic sterile compounding inspection at a nuclear pharmacy which also performs White Blood Cell Tagging. Investigator researched articles by several authors including the current expert UPS committee meeting minutes from the April 2016 meeting which indicates WBC tagging is medium risk and that it should be compounded in a true Buffer Area, not a Segregated Compounding Area.

Respondent pharmacy is currently designed as an SCA. Respondent's reply indicated there are no plans to comply with medium risk requirements. Investigator found the following areas of concern in this pharmacy:

Medium risk sterile compounding was being performed in an area that does not meet Buffer Area ISO Class 7 or better air standards or primary engineering control/facility and design standards. Respondent facility compounding area does in fact meet structural requirements to be classified as an ISO Class 7 area, but Respondent does not label it as such or apply applicable standards for testing.

Pharmacy technician admitted that more than one WBC tagging might occur is the same BSC at the same time.

One pharmacy technician was found to be wearing nail polish.

CETA certification report noted that the Anteroom ACPH was not compliant with USP 797.

Hand towels were not listed as lint free.

A ceiling tile in the anteaarea appeared to be loose.

Prior Discipline: None

Recommendation: 1 year monitoring, pay costs of investigation

Dr. Wilson made the motion to issue a cease and desist until the pharmacy is compliant with USP 797. Dr. Eidson seconded the motion. The motion carried. Dr. Pryse was recused.

Case 41.

BOP Investigator interviewed pharmacy staff regarding employee pilferage listed on a DEA 106 form showing a loss of 500 Hydrocodone APAP 10/325. While being interviewed, an assistant store manager, who is also a registered technician, confessed and provided a written voluntary statement that he had become addicted, had run out of legitimate prescriptions, had bought some on the street and then had an opportunity to grab and conceal a bottle while in the pharmacy. Technician registration had expired 3/31/2009 and is still expired.

Prior Discipline: None

Recommendation: Flag to not allow renewal

Dr. Smothers made the motion to accept counsel's recommendation. Ms. McDaniel seconded the motion. The motion carried.

Case 42.

Complainant patient alleged unprofessional conduct by pharmacy staff members. Complaint alleges staff made racial remarks and asked why the patient was coming there when patient presented a Hydrocodone prescription from a pain clinic.

BOP Investigator interviewed staff members. None remembered this particular incident but all denied that this type behavior would ever take place. Investigator attempted to call complainant for more information but the phone number provided by the complainant has either been changed or disconnected. The allegations could not be confirmed.

Prior Discipline: None

Recommendation: Dismiss

Dr. Smothers made the motion to dismiss the complaint. Ms. McDaniel seconded the motion. The motion carried.

Case 43.

Anonymous complaint alleged pharmacy PIC was unprofessional by misrepresenting errors and safety concerns made by another pharmacist who is also behaving unprofessionally.

BOP Investigators could not find evidence showing any violation of pharmacy laws.

Prior Discipline: None

Recommendation: Dismiss

Dr. Eidson made the motion to dismiss the complaint. Dr. Smothers seconded the motion. The motion carried.

Case 44.

This is the other pharmacist mentioned by complainant in Case 43 above.

Prior Discipline: None

Recommendation: Dismiss

Dr. Eidson made the motion to dismiss the complaint. Dr. Smothers seconded the motion. The motion carried.

Case 45.

This is the pharmacy involved in Cases 43 and 44 above.

Prior Discipline: None

Recommendation: Dismiss

Dr. Eidson made the motion to dismiss the complaint. Dr. Smothers seconded the motion. The motion carried.

Case 46.

Complainant pharmacist alleged pharmacy PIC was unprofessional by misrepresenting errors and safety concerns made by another pharmacist who is also behaving unprofessionally. Complainant alleged the PIC was not onsite enough to fulfill duties as PIC. Complainant alleged she was unlawfully terminated.

Complainant provided volumes of documents including timesheets, staff meeting notes, personal notes, timelines, descriptions of medication processes, protocol for anticoagulation therapy, notes on conversion of IV to PO or per tube, automatic stop date orders for medications, dosage rounding

guidelines, duplicate medication policy, scope of care and services, medication error reporting policies, competency assessment policy, high alert medication policies, parenteral nutrition policy, code of conduct, pharmacokinetic dosing, job descriptions, performance evaluations, policy on pharmacy related medication variances, and a letter of resignation.

BOP Investigators interviewed complainant by telephone attempting to potentially get more specific allegations that could be researched.

Investigators also visited the pharmacy and interviewed staff. Pharmacists and support staff all deny any wrongdoing and told investigators who they suspect made all of the complaints.

There appears to have been a lot of internal friction between staff members at the pharmacy. Complainant may have legitimate concerns involving personnel issues which are not within BOP jurisdiction. Investigators educated PIC on responsibilities and time requirements and suggested PIC appoint a new PIC so she can devote more time to management duties she shares between two hospitals.

Although the documentation was extensive and the investigation was thorough and very time consuming, there was no evidence found to substantiate the allegations.

Prior Discipline: None

Recommendation: Dismiss

Dr. Eidson made the motion to dismiss the complaint. Dr. Smothers seconded the motion. The motion carried.

Express Script

Dr. Rich Palombo, Sr. Director of Pharmacy Regulatory Affairs and Dr. Chris Meilinger, Sr. Director, Specialty Pharmacy Practice for Accredo Health Group, appeared before the board to ask for approval to implement a Unit of Use Automated Dispensing and Technology Assisted Dispensing of manufacturer's unit of use packaged drug products. The use of the pharmacy automation and barcode technology will be in the final verification of the prescription prior to being dispensed to the patient. After discussion, Dr. Eidson made the motion to approve this machine for Accredo Health Group located in Nashville and Memphis, TN only. Ms. McDaniel seconded the motion. The motion carried. Any changes to the business model, Accredo must notify the board.

Appearances

William Austin, D.Ph.

Dr. Austin answered yes to the question that asked "Are you presently under investigation or is there any disciplinary action pending against you by any licensing jurisdiction, the federal Food and Drug Administration, the federal Drug Enforcement Administration, or any state drug enforcement authority

for violation of any state or federal pharmacy, liquor, or drug laws?" Dr. Austin is in a pretrial diversion program that started March 17, 2016 for obtaining a controlled substance by fraud. The MS Board of Pharmacy issued him a Letter of Warning. After discussion, Dr. Smothers made the motion to approve Dr. Austin application for licensure by reciprocity once all the required documentation has been submitted. Ms. McDaniel seconded the motion. The motion carried.

Kenneth Pettengill, D. Ph.

Dr. Pettengill answered yes to the following questions: Have you ever voluntarily surrendered your pharmacist license or any pharmacist registration issued by a federal or state controlled substance authority?; Has your pharmacist license in any jurisdiction ever been revoked, suspended, restricted, terminated or otherwise been subject to disciplinary action (public or private) by any board of pharmacy or other state authority?; Have; you ever been charged or convicted (including a nolo contendere plea or guilty plea) of a felony or misdemeanor (other than a minor traffic offenses) whether sentence was imposed, suspended, expunged, or whether you were pardoned from such offense?. Dr. Pettengill's Florida pharmacy license was suspended in March 2009. Petition and was granted reinstatement with probation for 5 years. FL pharmacist license is active and in good standing. September 1987 pretrial intervention for sale of alcohol to a minor; October 2002, DUI and given probation; March 2007 arrested for trafficking and possession of illegal drugs and narcotic equipment. Charges dismissed after successful completion of drug court diversion; September 2007 failure to redeliver leased property (rental car). Case dismissed upon restitution and completion of drug court diversion. December 2007 worthless checks, case dismissed upon restitution. After discussion, Ms. McDaniel made the motion to approve Dr. Pettengill's application for licensure by reciprocity once all the required documentation has been submitted. Dr. Smothers seconded the motion. The motion carried. Dr. Dickenson voted no.

Jesica Patino, RT

Ms. Patino answered no to the question that asked "Have you ever been charged or convicted (including nolo contendere plea or guilty plea) of a felony or misdemeanor (other than a minor traffic offenses) whether or not sentence was imposed, suspended, or expunged, or whether you were pardoned from any such offense?" Documentation submitted indicates that Ms. Patino was found guilty on September 9, 2011 for unsafe condition of vehicle, controlled substance violations, no insurance. She was arrested on 9/7/2012, for simple assault, aggravated assault, domestic violence and telephone or electronic communication: obscene, indecent, annoying, threatening or harassing. After discussion, Ms. McDaniel made the motion to approve Ms. Patino's application for registration as a pharmacy technician. The motion died for lack of second. After further discussion, Dr. Smothers made the motion to Ms. Patino's application for registration as a pharmacy technician. Ms. McDaniel seconded the motion. The motion carried. Dr. Eidson and Dr. Dickenson voted no.

Application Review
Medisca, Inc.

Medisca, Inc., is applying as new business license for wholesaler/distributor in TN. They have two additional licenses in TN that are on indefinite probation beginning May 15, 2013 for violating T.C.A. § 53-10-305 (1), (2), (4) & (5). Documentation submitted shows that one of the owners was found guilty

of federal perjury before a grand jury May 7, 1998. He was given 1 day probation and fined \$1000.00. He also pled guilty to “causing the introduction into interstate commerce of a misbrand drug” on Marcy 14, 2012 and was ordered to pay a \$5000.00 fine. After discussion, Dr. Smothers made the motion to deny Medisca’s application for new business as a wholesaler/distributor. Dr. Dickenson seconded the motion. The motion carried.

Waivers

Board rule 1140-01-.13 (d) & (e)

Dr. Eidson made the motion to approve the request from **DMRx The Ranch** for an automated dispensing machine that the pharmacy to be 180 square feet and the requirement for hot and cold running water and to notify the board if the business model changes. Dr. Dickenson seconded the motion. The motion carried.

Dr. Wilson made the motion to approve the request from Premier Care Tennessee dba Ten Broeck Tennessee for an automated dispensing machine that the pharmacy to be 180 square feet and the requirement for hot and cold running water and to notify the board if the business model changes. Ms. McDaniel seconded the motion. The motion carried.

Board rule 1140-03-.14 (12)

Dr. Eidson made the motion to approve the request from **Paul Orgain, D.Ph.** to be the pharmacist in charge of the automated dispensing machine at DMRx The Ranch and DMRx, LLC “Dickson Medical Pharmacy”. Dr. Dickenson seconded the motion. The motion carried.

Dr. Dickenson made the motion to approve the request from **Rodney McCormick, D.Ph.** to be the pharmacist in charge of P & P Compounding Shop and First Choice Home Infusion. Ms. McDaniel seconded the motion. The motion carried.

Dr. Smothers made the motion to approve the request from **Marisol Limestone, D.Ph.** to be the pharmacist in charge of InTouch Pharmacy, Dawsonville, GA and East Ridge, TN. Ms. McDaniel seconded the motion. The motion carried.

Dr. Wilson made the motion to approve the request from **Amy Campbell, D.Ph.** to be the pharmacist in charge of the automated dispensing machines at Manchester Healthcare Center, Manchester, TN and Glen Oaks Health and Rehabilitation, Shelbyville, TN. Ms. McDaniel seconded the motion. The motion carried.

Board rule 1140-01-.07 (3)(b) 5 (ii) & (iii)

Dr. Smothers made the motion to approve the request from **Sheila Breeland, D.Ph.**, to waive the one hundred and sixty (160) internship hours but she must successfully take and pass the MPJE. Dr. Eidson seconded the motion. The motion carried.

Dr. Dickenson made the motion to approve the request from **Christy Harris, D.Ph.**, to waive the one hundred and sixty (160) internship hours but she must successfully take and pass the MPJE. Ms. McDaniel seconded the motion. The motion carried.

Consent Orders

Dr. Smothers made the motion to accept the following consent orders as presented. Dr. Wilson seconded the motion. The motion carried.

VIOLATED BOARD RULE 1140-03-.11

Fred's Pharmacy #2186, lic #2359
Smoky Mountain Pharmacy

PROBATION

Jacob Randolph Winn, D.Ph.

REINSTATEMENTS

Brian Cole, D.Ph.
Jeremy Joiner, D.Ph.
Robert Kilpatrick, D.Ph.
Matthew Zeleznak, D.Ph.

AGREED ORDER

Hampton Pharmacy, lic #3475

VIOLATED BOARD RULE 1140-03-.01 (1)(a) & (f)

Christopher Heasley, D.Ph.
Tennessee CVS Pharmacy #6429

VIOLATED BOARD RULE 1140-03-.02

Food City Pharmacy #674, lic #3640

VOLUNTARILY SURRENDER (revoked)

Mehr Drug Store
Glen Bonifield, Jr., D.Ph.

REVOKED

Debbie Ezell, RT
Michael E. Robinson, RT
Beverly Spray, RT (Agreed Order)

VIOLATED BOARD RULE 1140-01-.08 (1)

Specialized Medical Services, Inc.

ORDER MODIFICATION

T. Patrick Rowan, D.Ph.

BOARD RULE 1140-9-05(1)(b) (d) (e), (3), (6) and (7)
A.K. Medical Supply Company, Inc.

Presentation

Dr. Mitchell Mutter, Director of Special Project, appeared before the board to present an update of the Chronic Pain Guideline and to ask the board for approval of the policy changes. The board will vote to accept the updates at the September 20-21, 2016 board meeting.

Director's Report

Dr. Dilliard informed the board of Public Chapter 942 that allows a pharmacist to provide hormonal contraceptives according to a valid collaborative pharmacy practice agreement containing a non-patient-specific prescriptive order and standardized procedures developed and executed by one or more prescribers in certain circumstances. Dr. Dilliard asked the board to nominate someone to participate on a committee with the Board of Medical Examiners and Board of Osteopathic Examiners to write the rules for this requirement. Dr. Pryse and Ms. McDaniel were nominated to the committee.

Dr. Dilliard asked the board to form a committee to discuss rule changes. After discussion, Dr. Eidson and Dr. Smothers will be on the rules committee with Dr. Dilliard. Dr. Dilliard stated that he would like to present a statute change concerning T. C. A. 63-10-216 (a) which states "Prior to initial licensure in this state as a compounding pharmacy, a pharmacy located outside of this state must have an inspection by the regulatory or licensing agency of the state in which the pharmacy practice site is physically located. Out-of-state pharmacy practice sites must provide a copy of the most recent inspection by the regulatory or licensing agency of the state in which the pharmacy practice site is physically located, which must have been within the previous twelve (12) months. Prior to renewal of its license in this state, an out-of-state pharmacy practice site must provide the most recent inspection by the regulatory or licensing agency of the state in which the pharmacy practice site is physically located or equivalent regulatory entity, and which must have been within the previous twelve (12) months. The board of pharmacy shall have the right to require additional information before issuing or renewing a pharmacy license to insure compliance with applicable laws of this state and any rules and policies of the board." Dr. Dilliard stated that some states are using NABP/ VPP to conduct the inspection for sterile compounding and according to the statute we are not allowed to accept inspection not completed by the board of pharmacy in that state.

Dr. Dilliard informed the board that NABP will be changing the waiting period to retake the NABPLEX from a 91 day waiting period to a 45 day waiting period with a limit of 3 attempts within a 12 months period. The change will take effect on November 1, 2016.

The meeting adjourned at 3:45 p.m.

July 27, 2016

The Tennessee Board of Pharmacy reconvened on Wednesday, July 27, 2016 in the Iris Room, 665 Mainstream Drive, Nashville, TN. A quorum of the members were present, the meeting was called to order at 9:05 a.m., by Dr. Bunch, president.

Order Modification

T. Pat Rowan, D.Ph.

Dr. Rowan appeared before the board to request that he be allowed to float. Dr. Rowan's signed a consent order on 11/20/2015 placing his pharmacist license on 5 year probation and he would not be allowed to float for 2 years. After discussion, Dr. Smothers made the motion to amend Dr. Rowan's consent order and allow him to become a floater. Ms. McDaniel seconded the motion. The motion carried.

Contested Case

Broady Michael Allison, RT

Mr. Allison was not present nor represented by legal counsel. Mr. Cange represented the State. Mr. Rob Wilson was the Administrative Law Judge. Mr. Cange asked to proceed in default. The board granted the motion to proceed in default. Mr. Cange passed out the Notice of Charges. Mr. Allison is charged with violating board rule 1140-2-.02(1) and T. C. A. §63-10-305(g). Dr. Smothers made the motion to assess a \$50.00 civil penalty and case cost. Ms. McDaniel seconded the motion. The motion carried. Dr. Eidson made the motion that the action taken was to protect, promote and improve the health and prosperity of people in Tennessee. Dr. Dickenson seconded the motion. The motion carried.

Chirique Joyceia Lee, RT

Ms. Lee was not present nor represented by legal counsel. Mr. Cange represented the State. Mr. Rob Wilson was the Administrative Law Judge. Mr. Cange asked to proceed in default. The board granted the motion to proceed in default. Mr. Cange passed out the Notice of Charges. Ms. Lee is charged with violating T.C.A. §53-10-104(a) and (b), T.C.A. §53-10-105(a) and T.C. A. §63-10-305(4) & (6). After discussion, Dr. Wilson made the motion to revoke Ms. Lee's registration as a pharmacy technician and assessed case cost. Ms. McDaniel seconded the motion. The motion carried. Dr. Smothers made the motion that the action taken was to protect, promote and improve the health and prosperity of people in Tennessee. Dr. Eidson seconded the motion. The motion carried.

HealthMax Pharmacy, LLC

Christian Ifeanyi Onuh, D.Ph.

Dr. Onuh was presented and represented by Mr. Dan Warlick, Attorney. Mr. Cange represented the State. Mr. Rob Wilson was the Administrative Law Judge. Dr. Onuh is the owner of HealthMax Pharmacy, LLC and the pharmacist in charge. Mr. Onuh and HealthMax Pharmacy, LLC were charged with violating board rules 1140-02-.01(1), (3) and (4), 1140-11-.06(2), 1140-01-.02(1), and T.C.A. 63-11-401 (a)(1). During the board's lunch break a settlement was reached and an Agreed Order was

presented. Dr. Onuh agreed to the following terms: Dr. Onuh's Tennessee pharmacist license will be placed on probation for five (5) years, he cannot dispense controlled substance while on probation, complete twenty (20) hours of continuing education in addition to his required hours (hours must be approved by the executive director), HealthMax Pharmacy, LLC shall be sold within one (1) year of the date of ratification of this order. Dr. Onuh must appear before the board to request any modification to this order. Dr. Onuh must also pay a \$5000.00 civil penalty within 300 days from the ratification of this order, case and investigative cost. Dr. Dickenson made a motion to accept the Agreed Order as presented. Dr. Wilson seconded the motion. The motion carried.

General Discussion

Andrea Huddleston, General Counsel, informed the board that Mr. Cange will no longer be legal counsel for the board and that Matt Gibbs will be the board's new attorney. Mr. Cange will be assigned to the Board of Nursing. Ms. Huddleston stated the Mr. Cange will assist Mr. Gibb with the files in the Office of General Counsel.

Dr. Eidson asked if a pharmacy technician with an expired registration starts working at as a new hire, do they fall under the 90 day rule for registration. Pursuant to board rule 1140-02-.02 (2) (a) Any individual performing tasks that may be performed by a pharmacy technician who is classified by the employer as a probationary employee. The exemption shall not exceed ninety (90) days from the date of employment. After discussion, the board stated that if a pharmacy technician that has previously been registered starts working as a new hire, the 90 day rule applies.

The meeting adjourned at 1:53 p.m.

The minutes were approved and ratified at the September 20-21, 2016 board meeting.